UNITED STATES DISTRICT COURT
District of New Jersey

CHAMBERS OF
JOSE L. LINARES
JUDGE

MARTIN LUTHER KING JR.
FEDERAL BUILDING & U.S. COURTHOUSE
50 WALNUT ST., ROOM 5054
P.O. Box 999
Newark, NJ 07101-0999
973-645-6042

NOT FOR PUBLICATION

LETTER-OPINION & ORDER

June 13, 2006

VIA ELECTRONIC FILING

Andrew T. Berry, Esq.
Nicole A. Corona, Esq.
William J. Heller, Esq.
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
P.O. Box 652
Newark, NJ 07101

Gregory D. Miller, Esq.
Podvey, Meanor, Catenacci, Hildner,
Cocoziello & Chattman
A Professional Corporation
The Legal Center
One Riverfront Plaza
Newark, New Jersey 07102

Re: Altana Pharma AG, et al. v. Sun Pharmaceutical Industries Ltd., et al.
Civil Action No.: 05-3920 (JLL)

Dear Counsel:

This matter is before the Court by way of Plaintiffs Altana Pharma AG and Wyeth's (hereinafter "Plaintiffs") motion to dismiss Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Advanced Research Centre's (hereinafter "Defendants") third and fourth counterclaims pursuant to Fed. R. Civ. P. 12(b)(1). The motion is resolved without oral argument. Fed. R. Civ. P. 78. For the reasons stated herein, Plaintiffs' motion is granted without prejudice.

BACKGROUND AND PROCEDURAL HISTORY

As the Court writes only for the parties, a familiarity with the underlying facts in this case will be assumed. Plaintiffs' Complaint against Defendants for patent infringement, of Plaintiffs' United States Patent No. 4,758,579 ("the '579 patent"), was filed on August 5, 2005. Defendants' filed their Answer and Counterclaims, in part for a declaratory judgment of invalidity and non-infringement of Plaintiffs' United States Patent No. 6,780,881 ("the '881 patent"), on September 21, 2005. Only Counts III and IV of Defendants' counterclaims involve the '881 patent, thus they are the counts Plaintiffs presently seek to dismiss.

This case involves two patents involved in a drug called Protonix IV, which is designed to treat gastroesophageal reflux disease or, as more commonly known, heart burn and its more extreme forms. Plaintiffs developed the drug and filed with the FDA a detailed study about its safety and utility as well as patent numbers and expiration dates. Protonix IV is the injectable form of Protonix and its patent is comprised of the compound patent, the '579 patent, and the formulation patent, the '881 patent. The '579 patent identifies pantoprazole sodium as the active ingredient. The '881 patent covers the process for the production of a freeze-dried preparation of pantoprazole and is the subject of this motion and Counts III and IV of Defendants' counterclaims.

Pursuant to the Hatch-Waxman Act, Defendants filed an Abbreviated New Drug Application ("ANDA") to show that the drug they wished to market is the biological equivalent of an already patented drug, thereby avoiding having to prove the safety or efficacy of the drug to the FDA. Defendants, as generic drug producers wishing to enter the market *before* the expiration of a patent, also filed a "Paragraph IV" Certification with the ANDA, advising that the generic drug does not infringe the patent or, otherwise, that the Plaintiffs' patents are invalid.

Upon receipt of notice of the Paragraph IV Certification, Plaintiffs brought suit against Defendants on only the '579 patent. Plaintiffs assert that they have never asserted the formulation patent, the '881 patent, against Defendants or anyone else.

Defendants assert three sets of facts supporting their argument that they have a reasonable apprehension of suit: (1) during a conference call about their public quarterly earnings with securities analysts, the CFO of Wyeth stated that they intended to vigorously enforce and defend their patents in response to the ANDA seeking approval to market the generic version of Protonix, (Hand Cert. Ex. 1); (2) Plaintiffs declined to give Defendants a covenant or assurance not to sue, (Hand Cert. Ex. 3); and (3) Plaintiffs' litigation history on the '579 patent. Presently, Plaintiffs have two other infringement actions involving the '579 patent (*Altana Pharma and Wyeth v. Teva Pharms. USA, Inc., et al.*, Civil Action No. 04-2355 (JLL); and *Altana Pharma and Wyeth v. Sun Pharms. Indus. Ltd., et al.*, Civil Action No. 05-1966 (JLL)).[1] In Civil Action

[1] These two cases were consolidated on June 20, 2005. Civil Action No. 04-2355 is designated as the lead case. These actions involve Protonix, which is in tablet form, as opposed

No. 05-1966, Plaintiffs provided Defendants with a letter stating that they had no plans to assert one of the patents against Defendants. (Hand Cert. Ex. 2).

DISCUSSION

This motion is brought pursuant to Fed. R. Civ. P. 12(b)(1) to dismiss based on lack of subject matter jurisdiction. Article III of the Constitution, which is embodied in the Declaratory Judgment Act, requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgement. Teva Pharmaceuticals USA, Inc., v. Pfizer Inc., 395 F.3d 1324, 1331 (Fed. Cir. 2005), rehearing denied en banc, 405 F.3d 990 (Fed. Cir. 2005), cert. denied, 126 S. Ct. 473 (2005). "Whether there is an actual controversy between parties depends on whether the facts show that there is a substantial controversy between parties 'of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Teva v. Pfizer, 395 F.3d at 1333 (citing Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941)). The Federal Circuit has established a two-part test for declaratory judgment in cases involving patents to show that there is actual cause. Under this test, the party seeking jurisdiction must show "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." BP Chem. v. Union Carbine Corp., 4 F.3d 975, 978 (Fed. Cir. 1993) (citing Jervis B. Webb Co. v. Southern Sys., Inc., 742 F.2d 1388, 1398-99 (Fed. Cir. 1984)).

Here, Plaintiffs concede that Defendants have fulfilled the second prong of the test because Sun had already filed an ANDA with a paragraph IV certification with respect to the '881 patent.[2] Thus, only the first prong of the test is at issue here. Therefore, the issue before

---

to Protonix IV, which is in injectable form. The '579 patent is common to both Protonix and Protonix IV. Protonix is purported to comprise of the '579 patent and one other patent.

[2] Under the Federal Food, Drug and Cosmetic Act of 1938, otherwise known as the "Hatch-Waxman Amendments," companies that wish to market generic drugs must file an ANDA application with the FDA to prove that their generic version, as the therapeutic equivalent of the pioneer drug, is safe and effective. Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd., 325 F. Supp. 2d 502, 504 (D.N.J. 2004) (Linares, J.). Pioneer drugs are listed with their expiration date in the Orange Book. Apotex, Inc. v. Pfizer, Inc., 385 F. Supp. 2d 187, 188 (S.D.N.Y. 2005). ANDA applicants must certify whether the generic drug would infringe on the patents. Id (citing 21 U.S.C. § 355(j)(2)(A)(vii)). They can file either a paragraph I certification that the required patent information has not been submitted to the FDA, a paragraph II certification that the patent has expired, a paragraph III certification that the patent has not expired but is set to expire on a certain date, or a paragraph IV certification that the patent is invalid or will not be infringed by the new generic drug for which the ANDA is submitted. Glaxo, 325 F. Supp. 2d at 505 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV)). If an ANDA filer files a paragraph IV certification, as long

this Court is whether there is an explicit threat by Plaintiffs to put Defendants in reasonable apprehension that Plaintiffs will assert infringement of the formulation patent, the '881 patent, against Defendants.

Plaintiffs move to dismiss the Defendants' counterclaim for declaratory judgment on the '881 patent on the basis that the objective conduct of the Plaintiffs have not warranted Defendants having a reasonable apprehension of being sued on that patent. The focus of Plaintiffs' argument is based on Teva Pharms USA, Inc. v. Pfizer, Inc, 395 F.3d 1324, 1333 (Fed. Cir. 2005), and Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd., 325 F. Supp. 2d 502 (D.N.J. 2004). As in the present case, each of these cases involved situations where the patent(s) at issue had not been asserted in the initial infringement suit.

In viewing the totality of circumstance, Plaintiffs' conduct has not created a reasonable apprehension of an infringement suit on the '881 patent against Defendants. As mentioned above, the first prong of the test is key to determining if there is an actual controversy. Because there is no direct or express charge of pending suit on the '881 patent, this Court "must consider the 'totality of the circumstances' in determining whether . . . the facts alleged show that there is a substantial controversy between the parties 'of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Teva, 395 F.3d at 1333 (citation omitted). This requirement of imminence reflects the Article III mandate that the injury be "concrete" and "actual or imminent." Id. (citing Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 101 (1998)). The burden of proof rests on the party requesting declaratory judgment to establish that jurisdiction has existed at, and has continued since, the time the claim was filed. Sierra Applied Sciences, Inc. v. Advanced Energy Indus., 363 F.3d 1361, 1373 (Fed. Cir. 2004) (citation omitted).

First, there is no reasonable apprehension here because the Plaintiffs have never litigated on the '881 patent – only the '579 patent. There is no apprehension of being sued where the patentee's litigation history shows that they have only sued on some of a given product's patents, even if the patentee has refused to give a covenant not to sue. Glaxo, 325 F. Supp. 2d at 507. As Plaintiffs' moving brief noted, the fact that the patentee exhibited litigious tendencies with respect to some patents but not to others does not show a reasonable apprehension of litigation, especially where the patentee has filed suit on all other patents except the one at issue. Id. It is

---

as the patentee-pioneer drug producer sues within 45 days, the ANDA at issue cannot be approved until a judicial determination or after 30 months. Additionally, the first applicant to file an ANDA with a paragraph IV certification is eligible for a 180-day exclusivity period, during which the ANDA applicant can have sole generic entitlement to the pioneer drug. Apotex, 385 F. Supp. 2d at 188 (citing 21 U.S.C. § 355(j)(5)(B)(iv)). During this period, the FDA is "prohibited from approving any other ANDA involving the same brand name drug until the end of the exclusivity period." Id. Here, the Defendants have filed an ANDA with a paragraph IV certification. However, they are not the first ANDA filers of a paragraph IV certification alleging that the '579 patent is not infringed upon by their generic drug.

particularly significant that Plaintiffs could have sued on the '881 patent concurrently with its suit on the compound patent, but chose not to sue. Past and pending litigations have only been on the '579 patent and never on the '881 patent. Both Altana Pharma and Wyeth v. Teva Pharms. USA, Inc., 04-02355 (JLL), and Altana Pharma and Wyeth v. Sun Pharms. Indus. Ltd., Civil Action No. 05-1966 (JLL), concern patent '579 in the ANDA application for the tablet form Protonix, and the declaratory judgment action in Sun Pharms. Indus. Ltd. v. Altana Pharma AG., Civil Action No. 05-2391 (KSH), concerned a separate patent.

The Defendants argue unsuccessfully that Plaintiffs have shown intent to sue by providing a letter not to sue on a different patent in the past, but refusing to do so for the '881 patent. However, the Teva court has held that there is "nothing in the Federal Food, Drug and Cosmetic Act that requires [patentee] to respond one way or another to . . . [a] request for a covenant not to sue." Teva at 1331. Refusal by a patentee to give assurances it will not enforce a patent does not dispositively prove reasonable apprehension. BP Chem., 4 F.3d at 980. However, as "previous exhibited litigious tendencies" show that they will likely not sue on the '881 patent, the refusal to give a covenant is of no moment. Glaxo, 325 F. Supp. 2d at 507. Moreover, Defendants have cited no authority for the proposition that a patentee that provides a potential infringer with assurances concerning one of its patents obligates them to do the same for a different patent in another product.

In addition, the pledge made by the CFO of Wyeth that they will defend their patents vigorously is outweighed by the parties' past litigation history. As distinguished from the situation in Kos, the pledge to protect their patents vigorously is not a threat to litigate over any patent, related to the pioneered product, it owns. See Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc., 242 F. Supp. 2d 311, 317 (S.D.N.Y. 2003). As aforementioned, Altana's litigation history shows that it has not litigated every patent on the Protonix product. Additionally, the statements were made during a quarterly company review in reference to Protonix, before Protonix IV was even patented; thus the statements cannot apply to Patent '881, which is solely applicable to Protonix IV.

This Court disagrees with Defendants' argument that the asserted and unasserted patents concern similar or the same technology. See SmithKline Beacham Corp. v. Zenith Goldline Pharms., Inc., 2000 WL 963165, at *2 (E.D. Pa. June 28, 2000); Kos, 242 F. Supp. 2d at 315. They argue that the Plaintiffs' litigation history shows intent to sue because the two patents at issue are similar. They imply the patents are substantially similar because the cases at bar all involve patents for either Protonix or Protonix IV. However, in Kos the patents being litigated in the complaint and the unasserted patents were considered "nearly identical" because they not only treated the same disease, but involved the same composition. Kos, 242 F. Supp. 2d at 315. Here, the '579 patent is a compound patent and the '881 patent is a formulation patent, which serves the function of making Protonix injectable. It appears undisputed that the '579 and '881 patents neither serve similar purposes in the drug's design nor share any ingredients in their composition.

Defendants argue that the Glaxo case is immaterial because the parties in Glaxo had

already stipulated to a dismissal of parts of the counterclaim and merely wanted the court to give "its stamp of approval on a stipulation." Therefore, they argue its holding is distinct from this case. This Court does not agree with the Defendants' distinction of Glaxo and finds that its holding is applicable and binding here. In Glaxo, whether to incorporate the parties' privately negotiated settlement in a dismissal was altogether a separate issue; on which I ultimately decided against. Glaxo, 325 F. Supp. 2d at 508. I analyzed whether this Court had subject matter jurisdiction over the counterclaim after a third-party, who was also the first ANDA filer of the drug at issue, alleged that the execution of the stipulation would improperly dismiss the case *with* prejudice when this Court did not even have subject matter jurisdiction. Id. at 504. After a thorough analysis, I held that this Court lacked subject matter jurisdiction to hear the counterclaims and thus dismissed the counterclaims on the unasserted patent *without* prejudice. Id.

By statute, the patents at issue also lack actual controversy because the controversy is not "of sufficient immediacy" to provide this court with jurisdiction to issue a declaratory judgment on the '881 patent. Teva v. Pfizer, 395 F.3d at 1333. There is no "immediate" threat of being sued because if Teva, as the previous ANDA filer for the '579 patent, is successful, Teva will be entitled to a statutory exclusivity period, during which it is entitled to have the sole generic version of the pioneer drug on the market. Glaxo, 325 F. Supp. 2d at 505.

Lastly, this Court agrees with the Plaintiffs' argument that judicial efficiency will result from the dismissal of these counterclaims.[3] Altana v. Teva, Civil Action 04-2355 (JLL), and Altana v. Sun, Civil Action 05-1966 (JLL), were consolidated on June 20, 2005. As the consolidation Order stated, the cases involve at least common questions of law and fact concerning the '579 patent. As such, this Court concludes that the current action should also be consolidated with Altana v. Teva and Altana v. Sun, since this court dismisses Defendants' counterclaims involving the '881 patent.

For the above reasons, the totality of the circumstances demonstrate that there is no objectively reasonable apprehension by Defendants of being sued on the '881 patent. Therefore, Counts III and IV of Defendants' counterclaims, with respect to the declaratory judgment of non-infringement of the '881 patent, are hereby dismissed without prejudice for lack of subject matter jurisdiction.

CONCLUSION

For the foregoing reasons, it is on this 13th day of June, 2006,

O R D E R E D that Plaintiffs' motion to dismiss [CM/ECF Docket Entry #8] is GRANTED; and it is further

[3]Plaintiffs have represented to the Court that no further discovery will be necessary, in this action, on the '579 patent if the cases are consolidated. (Pl. Reply Br. at 11).

O R D E R E D that Defendants' counterclaims with respect to the Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,780,881 are DISMISSED WITHOUT PREJUDICE for lack of subject matter jurisdiction; and it is further

O R D E R E D that since this action, along with Altana v. Teva, Civil Action No. 04-2355 (JLL), and Altana v. Sun, Civil Action No. 05-1966 (JLL), involve at least common questions of law and fact surrounding United States Patent No. 4,758,579, the cases should be consolidated under the terms set forth in Magistrate Judge Hedges Order dated June 20, 2005.

/s/ Jose L. Linares
JOSE L. LINARES,
UNITED STATES DISTRICT JUDGE